STIPULATION REGARDING THE *HOLIDAY CVS* MATTER

The "Respondents" in the *Holiday* case (attached hereto) are: (1) CVS Pharmacy #219, located at 3798 Orlando Drive, Sanford, FL 32773; and (2) CVS Pharmacy #5195, located at 4639 W. First Street, Sanford, Florida 32771.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket Nos. 12–37 and 12–38]

Holiday CVS, L.L.C., d/b/a CVS/ Pharmacy Nos. 219 and 5195; Decision and Order

On June 8, 2012, Chief Administrative Law Judge (ALJ) John J. Mulrooney II, issued the attached Recommended Decision. Both parties filed Exceptions to the ALJ's decision.

Having considered the record in its entirety, including the parties' Exceptions, I have decided to adopt the ALJ's recommended rulings, findings of fact (except as discussed below), conclusions of law, and proposed sanction. A discussion of Respondents' Exceptions follows.[1]

[redacted]

PLAINTIFFS TRIAL EXHIBIT
P-42147-A

[redacted]

In enacting the Controlled Substances Act, Congress created a comprehensive and closed system for regulating the distribution of those controlled substances, which have legitimate medical uses, to prevent the diversion of these substances to those who would either abuse them or sell them to those who do. *See Gonzales* v. *Oregon,* 546 U.S. 243, 250 (2006). One of the fundamental features of this scheme is the requirement that all persons who seek to engage in the legitimate manufacture, distribution, or dispensing of a controlled substance must first obtain a registration from the Attorney General authorizing them to do so. *See* 21 U.S.C. 822(a). And to protect the public from those practitioners who engage in the diversion of controlled substances, Congress authorized the Attorney General to revoke the registration of a practitioner upon finding, *inter alia,* that the practitioner ''has committed such acts as would render his registration * * * inconsistent with the public interest.'' *Id.* sec. 824(a)(4).

It is manifest that Respondents' conduct in filling prescriptions issued by a practitioner whose registration had been revoked undermines the Congressional scheme. [redacted]

So too, those who engage in a highly regulated industry are expected to keep informed of regulatory developments which affect their industry. *See United States* v. *Southern Union Co.,* 630 F.3d 17, 31 (1st Cir. 2010) (''[T]hose who manage companies in highly regulated industries are not unsophisticated * * *. It is part of [a company's] business to keep abreast of government regulation.'').

Accordingly, Respondents' contention that the evidence does not establish that they (or their pharmacists) had actual knowledge of the revocation of Dr. Lynch's registration is wholly unavailing. Given that Respondents continued filling Lynch's unlawful prescriptions for more than six months after the Order became effective, and in the case of CVS #219 did so repeatedly, this conduct is sufficiently egregious [redacted]

[redacted] *Id.*

At the hearing, the Government presented extensive evidence showing that numerous persons, including persons who were not Florida residents, obtained prescriptions for both oxycodone 30 mg and alprazolam 2 mg from various South Florida physicians, whose offices were typically located 200 miles or more from Respondents (s*ee* GX 62), which they then presented to Respondents' pharmacists and which Respondents filled, notwithstanding that there are numerous pharmacies between South Florida and Sanford (where Respondents are located). The evidence included multiple spreadsheets showing each Respondent's dispensings of the oxycodone (and in some cases alprazolam) prescriptions issued by v[redacted]

The ALJ found credible Professor Doering's testimony that controlled substances are ''high alert drugs'' and that among controlled substances, drugs such as ''opioids, benzodiazepines, [and] other central nervous system depressant drugs'' require ''the highest level scrutiny'' on the part of a pharmacist who is presented with prescriptions for these drugs. Tr. 692; ALJ at 28. Professor Doering testified that in pharmacy practice, there are various red flags, which create ''a level of concern that might cause a pharmacist to either choose not to fill a prescription or take some other kind of actions,'' and that ''the more red flags there are, the stronger that suspicion is.'' Tr. 694. [redacted]

[redacted]

Professor Doering specifically identified such red flags as including that the patient is paying for controlled substance prescriptions with cash, *id.* at 703; the respective locations of the patient and the prescriber, *id.* at 701–02; that a prescriber writes for certain combinations or patterns of drugs, *id.* at 708; and multiple patients presenting ''prescriptions for the same drugs, the same quantities * * * from the same doctor without any kind of variability or change considering the different patients that come into the pharmacy,'' thus suggesting that the physician prescribes in a ''factory like manner.'' *Id.* [redacted]

[redacted]

[redacted]

[redacted]

The statements of Respondents' employees thus manifest a complete abdication of their responsibility ''to exercise professional judgment'' before dispensing prescriptions for highly abused controlled substances. *Ralph J. Bertolino, d/b/a/Ralph J. Bertolino Pharmacy,* 55 FR 4,729, 4,730 (1990). This evidence provides further support for the conclusions that each Respondent dispensed numerous prescriptions when their pharmacists either knew or had reason to know that the prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice and thus violated the CSA. *See* 21 CFR 1306.04(a).

[redacted]

[redacted]

In any event, even before many of the dispensings which are at issue here, this Agency had published several decisions which discussed the diversion and abuse of oxycodone, as well as drug cocktails which included oxycodone, alprazolam, and carisoprodol. *See Paul J. Volkman,* 73 FR 30,630 (2008) (discussing drug cocktails issued by physician for oxycodone, benzodiazepines and carisoprodol, expert testimony of abuse potential of these drugs, and red flag of patient travelling long distance to fill prescriptions); *see also East Main Street Pharmacy,* 75 FR 66,149 (Oct. 27, 2010) (discussing abuse of oxycodone, alprazolam, and carisoprodol and red flag of patients traveling long distances to fill prescriptions); *Your Druggist Pharmacy,* 73 FR 75,774, 75,775 n.1. (2008) (noting that ''[w]hile carisoprodol [was] not controlled under Federal law, it is controlled under various state laws and is highly popular with drug abusers, especially when taken as part of a drug cocktail that includes an opiate and a benzodiazepine''). Beyond this, the red flags presented by the circumstances of patients travelling from Kentucky or Tennessee to South Florida to obtain prescriptions, including for a schedule II narcotic, which by definition has the highest potential for abuse of any drug that may be prescribed lawfully, *see* 21 U.S.C. 812(b)(2), and then travelling to Respondents to fill them, are so obvious that only those who are deliberately ignorant would fill these prescriptions. I thus reject this contention as well.

I therefore conclude that the ALJ's finding that both Respondents repeatedly dispensed controlled substances in violation of 21 CFR 1306.04(a) is supported by substantial evidence.[28] ALJ at 69–70.

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[redacted]

[redacted]

In any event, Respondents diverted not only schedule II drugs, which have been placed in this schedule because they have the highest potential for abuse and the abuse of them ''may lead to severe psychological or physical dependence,'' *see* 21 U.S.C. 812(b)(2), but also schedule IV benzodiazepines.[32]

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This is more than enough to conclude that the revocation of the entirety of each Respondents' controlled substance dispensing authority is necessary REDACTED

[redacted]

REDACTED I therefore reject Respondents' contention that the ALJ's recommendation is overly broad and adopt the ALJ's recommended sanction.[33]

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration Number BC5289055, issued to Holiday C.V.S., L.L.C., d/b/a CVS Pharmacy #00219, and DEA Certificate of Registration Number BC6988298, issued to Holiday C.V.S., L.L.C., d/b/a CVS Pharmacy #5195, be, and they hereby are, revoked. I further order that any pending applications of Holiday C.V.S., L.L.C., d/b/a CVS Pharmacy #00219 or #5195, be, and they hereby are, denied. This Order is effective November 13, 2012.

Dated: August 31, 2012.

Michele M. Leonhart,

Administrator.

Paul Soeffing, Esq., Jason Hadges, Esq., Christine Menendez, Esq., for the Government

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[redacted] pharmacist has a ''corresponding responsibility under Federal law to dispense only lawful prescriptions.'' *Liddy's Pharmacy, L.L.C.,* 76 FR 48887, 48895 (2011). The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself. *Medicine Shoppe-Jonesborough,* 73 FR 364, 384 (2008) (Finding that a respondent pharmacy was properly charged with violating corresponding responsibility); *See also United Prescription Services, Inc.,* 72 FR 50397, 50407–08 (2007) (same). [redacted] Settled Agency precedent has interpreted this corresponding responsibility as prohibiting the filling of a prescription where the pharmacist or pharmacy ''knows or has reason to know'' that the prescription is invalid.[86] *Bob's Pharmacy & Diabetic Supplies,* 74 FR 19599, 19601 (2009) (citing *Medicine Shoppe-Jonesborough,* 73 FR at 381 (quoting *Medic-Aid Pharmacy,* 55 FR 30043, 30044 (1990))); [redacted]

[redacted]

Recommendation

REDACTED

. Consideration of the record evidence under the Fourth and Second Factors weighs in favor of revocation. The Respondents dispensed controlled substances where the prescribers were without authorization to prescribe, and under circumstances where a reasonable pharmacist would have concluded that the prescriptions were not issued for a legitimate medical purpose and in the usual course of a professional practice. The red flags that existed were recognized, or should have been, and the convincing expert evidence of record establishes that the red flags were not resolvable by a reasonable and professional pharmacist.

[redacted]